



PCT

To:

see form PCT/ISA/220 2v u

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/E2004/000057

International filing date (day/month/year)
16.04.2004

Priority date (day/month/year)
17.04.2003

International Patent Classification (IPC) or both national classification and IPC
A61L31/10, A61L29/08

Applicant
MEDTRONIC VASCULAR CONNAUGHT

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Thornton, S

Telephone No. +31 70 340-4182



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IE2004/000057

10/553546

Box No. I Basis of the opinion

JC20 Rec'd PCT/PTO 17 OCT 2005

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:
- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-14
	No: Claims	
Inventive step (IS)	Yes: Claims	1-14
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1023 PCT/IE2004/000057 17 OCT 2004

The following documents are referred to in this communication:

D1 : US 5 005 287 A
D2 : US 4 373 009 A
D3 : WO 98/58988 A
D4 : WO 00/30696 A

Clarity

The application does not meet the requirements of Article 6 PCT, because claims 1,6,8,12 are not clear. The statement "at least two polymeric species of differing molecular weights" is not clear as every polymer comprises at least two polymeric species of differing molecular weights. The polymers in question have different "weight average molecular weights" and in this communication the statement "at least two polymeric species of differing molecular weights" has been understood to mean at least two polymers of differing weight average molecular weights.

Novelty

D1 discloses a hydrophilic coating, e.g. for a razor, that comprises a water-soluble polymer or copolymer of polyvinyl pyrrolidone (PVP), at least one polymerisable vinyl monomer and a photoinitiator (see D1, column 2, line 36 to column 3, line 12; column 3, line 58 to column 4, line 14; examples; claims).

D2 discloses a coating for biomedical devices, e.g. catheters comprising polymers that can be produced using reactive diluents, e.g. N-vinyl pyrrolidone in the presence of benzophenone which causes the polymer to crosslink under ultraviolet light to give hydrophilic coatings (see D2, column 4, line 38-47; examples; claims).

D3 discloses a hydrophilic coating for biomedical devices comprising, e.g. PVP of two molecular weights, benzophenone, an acrylate prepolymer and a solvent (see D3, examples 7,8; claims).

D4 discloses a hydrophilic coating for biomedical devices comprising PVP which can also by UV irradiation be sterilised (see D4, page 6, line 23 to page 7, line 4; claims).

D1-D4 do not disclose a coating formulation comprising at least two polymers of different weight average molecular weights, an unsaturated hydrophilic monomer and a UV activatable compound as disclosed in independent claims 1,12. The subject-matter of claims 1,12 is therefore new in the sense of Article 33(2) PCT.

Inventive Step

The objective problem to be solved can be regarded as to provide improved hydrophilic coatings for biomedical devices which facilitates the passage of the coated device.

Document D1, which is considered to represent the most relevant state of the art, discloses a hydrophilic coating, e.g. for a razor, that comprises a water-soluble polymer or copolymer of polyvinyl pyrrolidone (PVP), at least one polymerisable vinyl monomer and a photoinitiator (see D1, column 2, line 36 to column 3, line 12; column 3, line 58 to column 4, line 14; examples; claims) from which the subject-matter of claims 1,12 differs in that the coating formulation comprises at least two (i.e. a blend of) polymers of different weight average molecular weights. The effect of having such a blend is "to optimise the hydrophilicity of the coating when wetted (cf. figure 1). The final coating on the surface of the medical device comprising an interpenetrating network has polymeric species of different lengths extending away from it which provides a means by which water may be trapped between the polymeric species when the surface is wetted, lending it hydrophilic and lubricious characteristics" (see present application, page 8, lines 1-20). It would not be obvious for a person skilled in the art from the teachings of D1 nor in combination with D2, D3 nor D4 to arrive at the solution proposed in the subject-matter of independent claims 1,12 of a coating formulation comprising at least two polymers of different weight average molecular weights, an unsaturated hydrophilic monomer and a UV activatable compound that would give rise to such an effect. Therefore, the solution proposed in the subject-matter of claims 1-14 is considered to involve an inventive step in the sense of Article 33(3).